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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,764	11/21/2006	Kenneth L. Weiss	91830.0523333	9938
26874 7590 01/28/2010 FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202				
EXAMINER ANSARI, TAHMINA N				
ART UNIT		PAPER NUMBER		
2624				
NOTIFICATION DATE		DELIVERY MODE		
01/28/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary

Application No.

10/598,764

Applicant(s)

WEISS ET AL.

Examiner

TAHMINA ANSARI

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 23-44 is/are rejected.
- 7) ☐ Claim(s) 18-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB006)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____
- 7) ☐ Notes of Informal Patent Application

DETAILED ACTION

1. Claims 1-44 are pending in this application.

Specification

2. The disclosure is objected to because of the following informalities.
 - Figure 16B is not properly described in the "Brief Description of the Figures".
 - Page 12 line 28, the use of element "block 46" with respect to Figure 1, appears to be a typo, as Figure 1 does not have any element with this label. For the purposes of the examination, this is being examined as "block 45".Appropriate correction is required.

Claim Objections

3. Claim 24 line 5 is objected to because of the following informalities: the word "representaiton" appears to be a typo for "representation". Appropriate correction is required.
4. Claim 34 line 3 is objected to because of the following informalities: the word "ot" appears to be a typo for "to". Appropriate correction is required.
5. Claims 1 and 13 are objected to because of the following informalities: the word "neuro axis" appears to be a typo for "neuro-axis". Appropriate correction is required.
6. Claim 43 line 2 is objected to because of the following informalities: the word "sectoion" appears to be a typo for "section". Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-7, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipp et al. (US PGPub US 2003/0086596 A1), hereby referred to as "Hipp", in view of Long et al. ("Landmarking and feature localization in spine x-rays", *J. Electron. Imaging*, Volume 10, Issue 4, pages 939-956, October 2001), hereby referred to as "Long".

Consider Claim 1:

Hipp teaches:

-“An apparatus comprising” (Hipp: [0002], [0009]-[0010], [0027], **Figure 1**):
-(a); “a memory configured to receive a medical diagnostic image representing a neuro axis of a patient” (Hipp: [0027]-[0029], **Figures 1 and 2; a memory configured to receive a medical diagnostic image [medical imaging data stored on disk tape or sent over a computer network, 2a]** representing a neuro axis [the spinal code, and thereby

the spine and its corresponding vertebrae are the axis to the central nervous system));

-(b); "a program stored in the memory and operatively configured to detect a plurality of spinal structures in said medical diagnostic image using an iterative process" (Hipp: [0028]-[0031], [0041]-[0047], **Figures 1 and 6; a program [software] stored in memory and operatively configured [a computer system is used consisting of a conventional computer, which would inherently have a processor and memory by which to operatively run the program] to detect spinal structures [individual vertebrae are tracked] iteratively [Figure 6];**

-(c); "a processor in communication with the memory to perform the program" (Hipp: [0027]-[0032], **Figures 1 and 2; the information handling system [1] consists of a processor [computer] that is in communication with the memory [RAM, ROM, storage disks, tapes, and other storage drives to store program information as well as medical images] to perform the program [software]).**

Hipp does not teach:

-(b); "to label a plurality of spinal structures".

Long, however does teach:

-(b); "to label a plurality of spinal structures" (**Long: page 941, section 2 "Goals, approach, and related work" paragraphs 2 and 5, pages 948-**

954, section 5.2 “Using the landmarks to locate the spine”; a plurality of spinal structures [vertebras] are labeled).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Hipp with the teachings of Long because they are both directed towards spinal imaging methods and systems, and because it would be desirable to combine a method for labeling landmarks and spinal features into a method and system for vertebrae localization and tracking. One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of Hipp with the teachings of Long which takes advantage of the “technical characterization of the cervical spine images and biomedical features of interest” in order to provide “segmentation of the images into vertebral structures with sufficient accuracy to distinguish pathology on the basis of shape, labeling of the segmented structures by the proper anatomical name, and classification of the segmented, labeled structures into groups corresponding to high level semantic features of interest” (Long: page 939 abstract).

Consider Claim 2:

The combination of Hipp and Long teaches “the apparatus of claim 1 wherein the program is operatively configured to utilize a region growth algorithm to identify a portion of the medical diagnostic image to analyze for the plurality of spinal structures” (Hipp: [0045]; Long: pages 945-948, section 5.1 “Finding basic

landmarks in the image”; seed-based region growing algorithms are used to identify a portion of medical diagnostic image to analyze for the plurality of spinal structures [anatomic and basic landmarks are used to identify locations for vertebral structures]).

Consider Claim 3:

The combination of Hipp and Long teaches “the apparatus of claim 1 wherein the program is operatively configured to detect and label a spinal structure based on a landmark, and is further operatively configured to detect and label an additional spinal structure based at least in part on a previously named and detected spinal structure **(Long: page 948, section 5.2 “Using the landmarks to locate the spine”, page 950 section 5.2.2 “Detecting the curves”; Long teaches using landmarks to identify and label spinal structures, and subsequent spinal structures are determined by previously named spinal structures [i.e. “for each i , let C_i be parameterized by t so that $C_i = [x_i(t), y_i(t)]$, and the search region D_i for new vertebrae is constrained by the previously identified vertebral structure).**

Consider Claim 4:

The combination of Hipp and Long teaches “the apparatus of claim 1 wherein the program is operatively configured to detect and label the plurality of spinal structures based at least in part on a landmark” **(Hipp: [0041]-[0046]; Long:**

pages 945-948, section 5.1 “Finding basic landmarks in the image”; basic landmarks are used to identify locations for vertebral structures).

Consider Claim 5: The combination of Hipp and Long teaches “the apparatus of claim 4 wherein the landmark is a top spinal structure” (Hipp: [0043], Figure 4b; Long: pages 945-948, section 5.1 “Finding basic landmarks in the image”; Hipp represents a landmark [18] in Figure 4, which is a top spinal structure, while Long teaches that basic landmarks include top spinal structures such as the skull, [SK]).

Consider Claim 6: The combination of Hipp and Long teaches “the apparatus of claim 4 wherein the landmark is a seed” (Hipp: [0045]; Long: pages 945-948, section 5.1 “Finding basic landmarks in the image”; seed-based region growing algorithms are used to identify a portion of medical diagnostic image to analyze for the plurality of spinal structures [anatomic basic landmarks are used to as seeds to identify locations for vertebral structures by region growing algorithms]).

Consider Claim 7: The combination of Hipp and Long teaches “the apparatus of claim 4 wherein the landmark is automatically detected” (Hipp: [0045]; Long: pages 945-948, section 5.1 “Finding basic landmarks in the image”, Table 3; Hipp teaches landmark points can be identified by a computer thereby

teaching automatic detection while Long teaches automatic landmarking and presents the results according to the different methods in a tabular format).

Consider Claim 13: The combination of Hipp and Long teaches "the apparatus of claim 1 wherein the medical diagnostic image corresponds to a superior portion of the neuro axis, and wherein the program is further operatively configured to combine the medical diagnostic image with a second medical diagnostic image corresponding to an inferior portion of the neuro axis" (Hipp: [0053]; Long: pages 941-942, section 3.1-3.2 "Characterization of the images: Global characteristics"-**"Spine region"**; Long teaches that a database of both cervical and lumbar spine images were used to determine a subset of 550 images to collect and determine coordinate data for both superior portions [cervical spine] and inferior portions [lumbar spine] of the neuro axis, while Hipp teaches a second medical diagnostic image corresponding to an inferior portion [lumbar vertebra] of the neuron axis).

Consider Claim 14: The combination of Hipp and Long teaches "the apparatus of claim 1 wherein the program is further operatively configured to analyze a spinal structure from the plurality of spinal structures" (Hipp: [0053]; Long: pages 941-942, section 3.1-3.2 "Characterization of the images: Global characteristics"-**"Spine region"**, pages 945-948, section 5.1 "Finding basic

landmarks in the image”; Long teaches that a database of both cervical and lumbar spine images were used to determine a subset of 550 images which were analyzed to determine a plurality of spinal structures [a plurality of spinal structures include cervical, thoracic, and lumbar vertebrae, as well as landmarks such as skull, and shoulder regions]).

Consider Claim 15: The combination of Hipp and Long teaches “the apparatus of claim 1 wherein the program is further operatively configured to produce a report based at least in part on the naming of the plurality of spinal structures” (**Long: page 939, section 1.2 “Future WebMIRS operation”; Long teaches producing a report [a searchable relational database that supports both image-based and content-based queries, and provides resultant data] based on the naming [labels] of the plurality of spinal structures [the vertebral labels, such as cervical, lumbar, thoracic, are fields available for query]).**

Consider Claim 16: The combination of Hipp and Long teaches “the apparatus of claim 1 further comprising a printer operable to produce a labeled visual representation of the medical diagnostic image on film” (**Hipp: [0027], Figure 1, element 6; Long, pages 953-954, section 5.2.7 “Results of computing the C_i^{**} , Figures 15a-b; Hipp teaches a printer operably connected to the**

imaging system, while Long teaches that visually labeled medical diagnostic film-based images are available).

Consider Claim 17: The combination of Hipp and Long teaches "the apparatus of claim 1 further comprising a screen operable to display the labeled visual representation of the medical diagnostic image" (Hipp: [0023], [0088], [0093]-[0096], Figure 1, element 5 Figures 14-15; Long: pages 947, section 5.1 "Finding basic landmarks in the image"; a display screen is used to visually represent the tracking results after tracking has been complete, while Long teaches displaying a labeled medical diagnostic image).

9. Claims 8-12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipp et al. (US PGPub US 2003/0086596 A1), hereby referred to as "Hipp", in view of Long et al. ("Landmarking and feature localization in spine x-rays", *J. Electron. Imaging*, Volume 10, Issue 4, pages 939-956, October 2001), hereby referred to as "Long", further in view of Kang et al. ("A new accurate and precise 3-D segmentation method for skeletal structures in volumetric CT data", *IEEE Transactions on Medical Imaging*, Vol. 22, No. 5, May 2003, pages 586-598), hereby referred to as "Kang".

Consider Claim 8:

The combination of Hipp and Long teaches "the apparatus of claim 1".

The combination of Hipp and Long does not teach:

-; "wherein the medical diagnostic image is comprised of a plurality of voxels, and wherein the program is further operatively configured to:

-(a); "identify a plurality of voxels in the medical diagnostic image as candidate spinal structures;

-(b); "apply a spinal structure constraint to identify a series of spinal structures comprising a subset of said candidate spinal structures".

Kang, however does teach:

-; "wherein the medical diagnostic image is comprised of a plurality of voxels, and wherein the program is further operatively configured to"

(Kang: pages 586-589, section IIA, Figure 2; the medical diagnostic image consists of a plurality of voxels that are identified):

-(a); "identify a plurality of voxels in the medical diagnostic image as candidate spinal structures" **(Kang: pages 586-589, section IIA-IB, Figure 2 and 7a; the medical diagnostic image consists of a plurality of voxels that are identified for labeling candidate spinal structures in a European spine phantom (ESP));**

-(b); "apply a spinal structure constraint to identify a series of spinal structures comprising a subset of said candidate spinal structures" **(Kang: pages 586-589, section IIA-IB, Figure 2 and 7a; the medical diagnostic image consists of a plurality of voxels that are identified for labeling a series of spinal structures in a European spine phantom (ESP), for labeling lumbar vertebrae).**

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Hipp and Long with the teachings of Kang as they are all directed towards spinal imaging methods and systems. One of ordinary skill in the art, at the time of the invention, would have been motivated to modify the combination of Hipp and Long with the teachings of Kang to apply a method and system for labeling landmarks and spinal features for vertebrae localization and tracking to the realm of computerized tomography. The combination of Hipp, Long and Kang teaches a method and system that provides an "automated three-dimensionally based-method for the segmentation of bone in volumetric computed tomography datasets" for spinal imaging (**Kang: abstract**).

Consider Claim 9:

The combination of Hipp, Long and Kang teaches "the apparatus of claim 8 wherein the program is further operatively configured to detect a plurality of voxels in the medical diagnostic image as candidate spinal structures by performing a calculation comprising comparing a voxel in the medical diagnostic image with a voxel in a second medical diagnostic image wherein the second medical diagnostic image corresponds to a sagittal section adjacent to a second section corresponding to the medical diagnostic image" (**Kang: pages 589-591, section IIB, Figure 7; sagittal image slices are used for comparison in the**

detection of voxels in spinal structures represented on medical diagnostic images).

Consider Claim 10:

The combination of Hipp, Long and Kang teaches "the apparatus of claim 8 wherein the program is further operatively configured to (a) identify a line defined in part based on a centroid of a candidate spinal structure in the series of spinal structures" (**Long: page 942, section 3.2 "Spine Region", page 948-954, section 5.2 "Using the landmarks to locate the spine"; the center of gravity is found for each of the vertebral structures and a straight line is fitted in the series of spinal structures**); "(b) identify an additional spinal structure by searching for a local intensity extreme along a region defined in part by the line" (**Kang: pages 588-589, section IIA, segmentation steps 3-4, Figure 4; local intensity extremes are searched for using thresholding, to help determine additional spinal structures**).

Consider Claim 11: The combination of Hipp, Long and Kang teaches "the apparatus of claim 10 wherein the region defined in part by the line is defined in further part by extending the line based on an estimate of a position for the additional disc" (**Long: page 948-954, section 5.2 "Using the landmarks to locate the spine", section 5.2.1 "Motivating the search for image surface curves in the spine region; a line [curve] is extended based on an estimate**

of a position for the additional discs using landmarks for skull and shoulder).

Consider Claim 12: The combination of Hipp, Long and Kang teaches "the apparatus of claim 10 wherein the region defined in part by the line is defined in further part by an additional line, the additional line being parallel to the line" **(Long: page 948-954, section 5.2 "Using the landmarks to locate the spine", Equations 1-4; Each C_i is determined to represent each vertebral disc, while an objective function $J(C_1, C_2, C_3, C_4)$ is used to represent the coupling between the discs, and is minimized to determine the structural representation of the spine, thereby teaching an additional line parallel to the line that is defined by the structural landmarks, the skull and shoulder).**

Consider Claim 23: The combination of Hipp, Long and Kang teaches "the apparatus of claim 1 wherein the program is further configured to reconstruct a slice by selectively applying a plurality of reconstruction algorithms based at least in part on the detection and labeling of the plurality of spinal structures" **(Kang: pages 589-591, section IIB, Figure 7; sagittal image slices are reconstructed based on the labeling of the spinal structures).**

10. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipp et al. (US PGPub US 2003/0086596 A1), hereby referred to as "Hipp", in view of

Long et al. ("Landmarking and feature localization in spine x-rays", *J. Electron. Imaging*, Volume 10, Issue 4, pages 939-956, October 2001), hereby referred to as "Long", further in view of Archip et al. ("A knowledge-based approach to automatic detection of the spinal cord in CT images", *IEEE Transactions on Medical Imaging*, Vol. 21, No. 12, December 2002), hereby referred to as "Archip".

Consider Claim 24:

The combination of Hipp and Long teaches:

-a; "the apparatus of claim 1 further comprising a screen wherein the program is operable to display a visual representation of the medical diagnostic image" (**Hipp: [0023], [0088], [0093]-[0096], Figure 1, element 5 Figures 14-15; Long: pages 947, section 5.1 "Finding basic landmarks in the image"; a display screen is used to visually represent the tracking results after tracking has been complete, while Long teaches displaying a labeled medical diagnostic image)**"

The combination of Hipp and Long does not teach:

-b; "display a visual representation of the medical diagnostic image using a first contrast and a second contrast, wherein the first contrast is used for portions of the visual representation corresponding with bone and wherein the second contrast is used for portions of the visual representation corresponding with soft tissue".

Archip, however, does teach:

-b; "display a visual representation of the medical diagnostic image using a first contrast and a second contrast, wherein the first contrast is used for portions of the visual representation corresponding with bone and wherein the second contrast is used for portions of the visual representation corresponding with soft tissue". (**Archip: page 1505, section II-IIA, section III, Figures 1 and 6; Archip teaches that both bone and soft tissue exist in medical diagnostic images [image slices], and provides visual representation of the different contrast that is used for bone tissue [white areas in Figures 1 and 6], in contrast with soft tissue [gray areas in Figures 1 and 6], and further teaches using the different HU levels to threshold out the appropriate issue type)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Hipp and Long with the teachings of Archip as they are all directed towards spinal imaging methods and systems. One of ordinary skill in the art, at the time of the invention, would have been motivated to modify the combination of Hipp and Long with the teachings of Archip to apply a method and system for labeling landmarks and spinal features for vertebrae localization and tracking to the realm of computerized tomography. The combination of Hipp, Long and Archip teaches a method and system that factors in adjustable image acquisition conditions, such as contrast administration, in order to provide the best visualization of the regions, and

lesions of interest for medical diagnosis and treatment (**Archip: page 1505, section IIA**).

Consider Claim 25:

The combination of Hipp, Long and Archip teaches "the apparatus of claim 24 wherein the first contrast and the second contrast are adjustable" (**Archip: page 1505, section IIA, Figures 1 and 6; Archip teaches that contrast administration, including presence/type of contrast, injection speed, and concentration are variable**).

11. Claims 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fichtinger et al. (US PGPub US 2006/0241368 A1), hereby referred to as "Fichtinger", in view of Hipp et al. (US PGPub US 2003/0086596 A1), hereby referred to as "Hipp".

Consider Claim 26:

Fichtinger teaches:

(a) "A method comprising: placing an imaging coil external to a neuro-axis of a patient wherein said imaging coil is adapted to a contour of the patient" (**Fichtinger: [0016], [0024]; an imaging coil is external to human body, and thereby external to the neuro-axis of the patient**);

(b) "obtaining a medical diagnostic image of a portion of the patient"

(Fichtinger: [0021], [0123], Figure 15; digital images of a patient are obtained using a medical diagnostic imaging apparatus such as an MRI, or CT);

(c) "identifying a position in the medical diagnostic image" **(Fichtinger: [0123]; a selected target position is identified in the medical diagnostic image by medical personnel);**

(d) "and autoprescribing an additional procedure for the identified position" **(Fichtinger: [0015], [0123]-[0124]; an additional procedure [biopsy, needle therapy or other therapeutic techniques] are auto-prescribed [computer, 1010, determines how much to rotate, translate the needle carrier, 154, from its present position to a final position where the needle exit port, 175, is at a allocation for deployment of the needle 350, and how much to insert the needle so that the needle will arrive at the three-dimensional coordinates corresponding to the target location).**

Fichtinger does not teach:

(b) "obtaining a medical diagnostic image of a portion of the neuro-axis of the patient".

Hipp teaches:

(b) "obtaining a medical diagnostic image of a portion of the neuro-axis of the patient" **(Hipp: [0027]-[0029], Figures 1 and 2; a memory**

configured to receive a medical diagnostic image [medical imaging data stored on disk tape or sent over a computer network, 2a] representing a neuro axis [the spinal code, and thereby the spine and its corresponding vertebrae are the axis to the central nervous system]].

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fichtinger with the teachings of Hipp because they are both directed towards methods and systems for localization of landmark features in medical imaging. One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of Fichtinger with the teachings of Hipp in order to provide an advantageous method and system for external medical imaging to further "process medical images via an information handling system" to identify spinal structures, acquire tracking data, and account for motion within the individual spinal structures (**Hipp [0008]**).

Consider Claim 27: The combination of Fichtinger and Hipp teaches "the method of claim 26 wherein the imaging coil is a flexible imaging coil" (**Fichtinger: [0072]-[0083], Figures 4-6; the imaging coil consists of tracking coils and registration coils both of which are coupled in flexible portions of the guide channel and the needle carrier and provides for a predetermined amount of rotation and translation, to allow for increased flexibility**).

Consider Claim 28: The combination of Fichtinger and Hipp teaches “the method of claim 26 wherein the imaging coil is adherent to the patient” (**Fichtinger: [0121]-[0122], Figure 15, element 400,600; a mounting mechanism allows for the imaging coil to adhere to the patient or subject).**

Consider Claim 29: The combination of Fichtinger and Hipp teaches “the method of claim 26 wherein the additional procedure comprises obtaining a second medical diagnostic image” (**Fichtinger: [0108], [0118]-[0119], Figure 14; the target tissues are re-imaged after insertion into the subject using the MRI imaging loop, thereby capturing a second medical diagnostic image).**

Consider Claim 30: The combination of Fichtinger and Hipp teaches “the method of claim 26 wherein the additional procedure comprises activation of a robotically actuated therapeutic instrument” (**Fichtinger: [0121]-[0126], Figure 15; the needle is automatically controlled by the computer, and thus serves as a robotically-actuated therapeutic instrument).**

Consider Claim 31: The combination of Fichtinger and Hipp teaches “the method of claim 26 wherein said imaging coil comprises a localizer” (**Fichtinger: [0122], Figure 15; the imaging coil comprises a localizer [end-effector, 150,152]).**

Consider Claim 32: The combination of Fichtinger and Hipp teaches “the method of claim 3 1 wherein the localizer comprises a sheath” (**Fichtinger: [0122], Figure 15; the imaging coil comprises a sheath [sheath, 152]**).

Consider Claim 33: The combination of Fichtinger and Hipp teaches “the method of claim 32 wherein the imaging coil is movable within the sheath” (**Fichtinger: [0119], [0122]-[0124], [0128], Figure 15 a; the needle carrier [154, 704] is movable within the sheath [sheath, 152], and has passive/active fiducials to assist imaging systems, thereby making the imaging coils in the interventional device [170c encodes rotation around the central axis], movable within the sheath**).

12. Claims 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (US Patent 6,011,061), hereby referred to as “Lai”, in view of Fichtinger et al. (US PGPub US 2006/0241368 A1), hereby referred to as “Fichtinger”.

Consider Claim 34:

Lai teaches:

-a; “A localizer system comprising a dye operable to create a marking on a surface of a patient” (**Lai: column 2 lines 55-67, column 3 lines 1-67, column 4 lines 1-56, Figure 1; a localizer system comprising a dye**

[rubidium chloride, a white compound] operable to create a marking on a surface of a patient [application to skin of a patient]],

Lai does not teach:

-b; "and a detectable region adapted for creating a reference on a medical diagnostic image corresponding to the marking".

Fichtinger teaches:

-b; "and a detectable region adapted for creating a reference on a medical diagnostic image corresponding to the marking" (**Fichtinger: [0096], [0121]-[0126], Figure 15; Fichtinger teaches the use of markers and seeds to localize a target site, and generating a medical diagnostic image that has a detectable region [target site] adapted for creating a reference corresponding to the marking).**

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Lai with the teachings of Fichtinger because they are both directed towards methods and systems for localization of landmark features in medical therapeutics. One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of Lai with the teachings of Fichtinger in order to provide an advantageous method and system to account for coordination of therapeutically treated areas in musculoskeletal disorders to an external medical imaging device, that can take advantage of using a computer controlled needle insertion and guiding technique (**Fichtinger: [0123]**) for "image-guided biopsy and/or a wide range of therapeutic

techniques" that can "maximize needle placement accuracy" (**Fichtinger: [0015]**).

Consider Claim 35: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 further comprising fabric" (**Lai: column 3 lines 1-14, lines 36-41**).

Consider Claim 36: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 further comprising an adhesive" (**Lai: column 3 lines 1-14, lines 36-41**).

Consider Claim 37: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region is fillable" (**Lai: column 3 lines 36-64; Fichtinger: [0098]; Fichtinger teaches that the detected region [target site] is fillable by therapeutic agents through the needle of the interventional device, while Lai teaches that the detectable region [skin area] is fillable, as the therapeutic dye of rubidium chloride is absorbed by the patient in the region**).

Consider Claim 38: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the localizer system comprises a plurality of plastic

sheets" (**Lai: column 3 lines 26-64, Figure 1; the localizer system comprises a plurality of plastic sheets).**

Consider Claim 39: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region comprises a grid" (**Fichtinger: [0083], [0123], Figure 15; the detectable region comprises a grid [coordinate system of an MRI scanner corresponds to grid-like data, allowing for the representation of the detectable region]).**

Consider Claim 40: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region comprises a movable portion" (**Fichtinger: [0015]; Lai: column 3 lines 35-67, column 4 lines 9-12; Fichtinger teaches that the detectable region [target site] comprises a movable portion [target tissues include areas surrounding any real or artificial opening, including prostate, rectum, vagina, and cervix, consisting of movable portions], while Lai teaches detectable region [skin area] comprises a movable portion [skin can be attached to an appendage such as a knee that is movable]).**

Consider Claim 41: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region is configured to indicate location" (**Fichtinger: [0015] Fichtinger: [0083], [0123], Figure 15; Lai:**

column 3 lines 35-67, column 4 lines 9-12; Fichtinger teaches that the detectable region [target site] indicates a location [target tissues include structural locations through the identification of prostate, rectum, vagina, and cervix, consisting of movable portions], and further comprises a grid [coordinate system of an MRI scanner corresponds to grid-like data, representing locations of the detectable region], while Lai teaches detectable region [skin area] comprises a location [skin can be attached to an appendage such as a knee that is movable]).

Consider Claim 42: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region is multimodality compatible" **(Fichtinger: [0016], [0119], Figure 15; multi-modality compatibility is taught through the use of any medical imager, including MRI, CT, X-ray fluoroscopy, ultrasound imaging, and that the interventional device includes an end-effector [700] that can leverage other imaging techniques thereby teaching multi-modality).**

Consider Claim 43: The combination of Lai and Fichtinger teaches "the localizer system of claim 34 wherein the detectable region comprises a first section and a second section" **(Fichtinger: [0015]; Lai: column 3 lines 35-67, column 4 lines 9-12; Fichtinger teaches that the detectable region [target site] comprises a first section [target site for biopsy] and a second section [tissue areas**

include areas surrounding any real or artificial opening, including prostate, rectum, vagina, and cervix, consisting of movable portions], while Lai teaches a detectable region comprises of a first section [skin area affected by disorder] and a second section [skin can be attached to an appendage such as a knee or an alternate body part such as a back]).

Consider Claim 44: The combination of Lai and Fichtinger teaches “the localizer system of claim 43 wherein the first section comprises a first material and the second section comprises a second material” (Fichtinger: [0015], [0019], [0036], [0038]; Lai: column 3 lines 35-67, column 4 lines 9-12; Fichtinger teaches that the detectable region [target site] comprises a first section [target site for biopsy] with a first material [target or cancerous cells] and a second section [tissue areas include areas surrounding any real or artificial opening, including prostate, rectum, vagina, and cervix] comprising a second material [other non-cancerous cells]).

Allowable Subject Matter

13. Claims 18-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter.

a. The prior art fails to teach the method of Claim 18, which specifically comprises the following features in combination with other recited limitations:

- The apparatus of claim 1 wherein the program is further operatively configured to ***automatically generate a prescription using said labeling of the plurality of spinal structures***

As these limitations were in claim 18, and claims 19-22 are dependent upon claim 18, and encompass the limitations specified in claim 18, thereby making them allowable subject matter as well.

Therefore, Claim 18 and its dependent Claims 19-22 are not rejected over the prior art.

Conclusion

14. The prior art made of record in form PTO-892 and not relied upon is considered pertinent to applicant's disclosure.

Porat; Hadar et al., US 20080132784 A1, Spine labeling.

Steiger; Peter et al., US 6002959 A, Morphometric x-ray absorptiometry (MXA).

Foley; Kevin T. et al., US 20060122483 A1, System for use in displaying images of a body part.

Jerebko; Anna et al., US 20080044074 A1, System and Method for Spinal Cord and Vertebrae Segmentation.

Bernard; Leo N., US 4294577 A, Dyed flocked fabric and method of making the same.

"Rubidium Chloride (MSDS)", Fisher Scientific Material Safety Data Sheet, A Fischer Scientific International Company, Created 12/12/1997, Revision #4, Date 3/18/2003, Downloaded 01/14/2010.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAHMINA ANSARI whose telephone number is 571-270-3379. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 571-272-7453. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 571-273-8300 for After Final communications. TC 2600's customer service number is 571-272-2600.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-2600.

/Andrew W Johns/
Primary Examiner, Art Unit 2624

2624
/TA/
January 14, 2010